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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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IM22/0619

W. S. 161 CON

EXAMINER

BROWN RUDNICK FREED & GESMER
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KIM, S
ART UNIT

PAPER NUMBER

3

1723
DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/803 570

Applicant(s)

FIEHLER, WILLIAM R.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-14, 16, 18-25, 27, 28 and 30 is/are rejected.
- 7) ☐ Claim(s) 15, 17, 26 and 29 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- Interview Summary (PTO-413) Paper No(s) _____
- Notice of Informal Patent Application (PTO-152)
- Other _____

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1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the oath does not claim the benefit under 35 USC 120 of parent application no. 08/762,358.

2. If applicant desires priority under 35 U.S.C. 120 and under 35 USC 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made

5. Claims 1-6, 11-14, 16, 18-25 and 27-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 4,257,886 (hereinafter referred to as Kessler). Kessler teaches a blood -collection device comprising a tube (10) with a hydrophobic coating (30) on the inner surface of the tube and thixotropic gel material (28) placed in a bottom inner central surface of the tube (10) with a syringe (see figures 1-3; col. 2, line 46 - col. 6, line 21). Hydrophobic coating is a non-stick coating for hydrophilic component of blood. Kessler teaches the method of placing blood in the above described tube and centrifuging blood (see figures 1-3). Furthermore, Kessler teaches that any means used to place the gel in the container adjacent the closed end of the tube is satisfactory so long as a transverse barrier is formed between the separated phase of the blood upon centrifugation of the device (see col. 3, lines 29-37). Defining the limits of gel to be placed in the tube would have been obvious to a person of ordinary skill in the art depending on the volume of blood to be separated.

6. Claims 7-10 and 30 (independently) are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler as applied to claim 5 above, and further in view of U.S. Patent No. 3,516,385 (Walling). Claims 7-10 and 30 essentially differ from the apparatus of Kessler in reciting a dispensing apparatus having a nozzle with a plurality of openings disposed about a portion of a circumference thereof through which gel is dispensed. Kessler teaches that any means used to place the gel in the container adjacent the closed end of the tube is satisfactory so long as a transverse barrier is formed between the separated phase of the blood upon centrifugation of the device (see col. 3, lines 29-37). Walling teaches that coating materials are

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coated in the interior of tubular members by a centrifugal distributor with nozzle having a plurality of openings disposed about a portion of a circumference thereof and the number and size of the openings and the speed of a lancer holding the centrifugal distributor will determine the thickness of the coating and inherently the shapes of the coating (see col. 7, line 41 - col. 9, line 50). It would have been obvious to a person of ordinary skill in the art to use the known coating apparatus having a nozzle with a plurality of openings to coat the inner surface of a tube with gel for separating blood components.

7. Claims 1-4, 12-14, 16 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,853,600 (hereinafter referred to as McNeal et al). McNeal et al teach a blood collection device comprising a tube (10) and thixotropic gel material (24) placed on the inner surface of the tube (10) in a form of discrete stripes or continuous bands (see figures 1-6; col. 2, line 60 - col. 4, line 46). McNeal et al teach the method of placing blood in the above described tube and centrifuging blood (see figures 1-6).

8. Claims 15, 17, 26 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for

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official response after final action is (703) 305-3599, and the fax phone number for all other official faxes is (703) 305-7718.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.



John Kim
Primary Examiner
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J. Kim
June 18, 2001